

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

THE UNIVERSITY OF PITTSBURGH –
OF THE COMMONWEALTH SYSTEM OF
HIGHER EDUCATION,

Plaintiff,

v.

KRYO, INC. and EBB THERAPEUTICS,
LLC.

Defendant.

Civil Action No. 2:21-cv-1724

JURY TRIAL DEMANDED

**COMPLAINT FOR BREACH OF CONTRACT,
UNJUST ENRICHMENT, AND PATENT INFRINGEMENT**

Plaintiff The University of Pittsburgh – of the Commonwealth System of Higher Education d/b/a The University of Pittsburgh (“the University”), through its undersigned counsel, files the instant Complaint against Kryo, Inc. (“Kryo”) and Ebb Therapeutics, LLC (“Ebb”; collectively, “Defendants”) for breach of contract, unjust enrichment, and infringement of U.S. Patent Nos. 9,089,400, 9,492,313, and 9,669,185 (the “Asserted Patents”) and states as follows:

The Parties

1. The University is a state-related university with its principal place of business at 4200 Fifth Avenue, Pittsburgh, Pennsylvania 15260. The University was founded in 1787 as a small, private school, known as the Pittsburgh Academy, which was located in a log cabin near Pittsburgh’s three rivers. In the 234 years since, the University has evolved into an internationally recognized center of learning and research. The University is one of the nation’s top research universities and has worldwide patent and intellectual property rights resulting from the activities of its faculty, staff, and students and from its commitment to support innovation. The University

has over 2,300 worldwide patents and over 1,350 U.S. patents in various fields. The University owns valuable intellectual property rights in this and other technology areas and is the assignee of, inter alia, the Asserted Patents.

2. Defendant Kryo, Inc. is a Delaware corporation with a principal place of business at 144 Talbert Pointe Drive, Suite 103, Mooresville, North Carolina 28117. Its registered agent for service is Incorporating Services, Ltd., 3500 S Dupont Highway, Dover, DE 19901. Kryo actively transacts business in Pennsylvania and offers, sells, and induces use of products infringing claims of the Asserted Patents in the Western District of Pennsylvania.

3. Defendant Ebb Therapeutics, LLC is a Delaware corporation with a principal place of business at 144 Talbert Pointe Drive, Suite 103, Mooresville, North Carolina 28117 and is a wholly owned subsidiary of Kryo. Ebb's registered agent for service is Incorporating Services, Ltd., 3500 S Dupont Highway, Dover, DE 19901. Ebb actively transacts business in Pennsylvania and offers, sells, and induces use of products infringing claims of the Asserted Patents in the Western District of Pennsylvania.

4. The Defendants have a regular and established place of business at 2555 Smallman St #100, Pittsburgh, PA 15222.

Jurisdiction and Venue

5. The University's causes of action arise, at least in part, from Defendants' contacts with and activities in this Western District of Pennsylvania and the State of Pennsylvania.

6. This action arises out of an Exclusive License Agreement (the "License Agreement") the University entered into with Defendant's predecessor-in-interest Ebb Therapeutics, Inc. f/k/a Cerêve Inc. (the "Licensee") on February 27, 2012. A true and correct copy of the License Agreement is attached hereto as Exhibit A.

7. Article 13.1 of the License Agreement states “[t]he forum for any action relating to this Agreement, including those brought against foreseeable third parties such as University employees, shall be the Courts of Allegheny County, Pennsylvania, or if in a federal proceeding, the United States District Court for the Western District of Pennsylvania.” This Court has jurisdiction over this action and venue is proper pursuant to the License Agreement.

8. This action also arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. §§ 271, 281, 284, and 285. This is a patent infringement lawsuit over which this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. This United States District Court for the Western District of Pennsylvania has personal jurisdiction over Defendants because Defendants regularly conduct and solicit business in, engage in other persistent courses of conduct in, and/or derive substantial revenue from goods and services provided to residents of this District and the State of Pennsylvania via at least Defendants’ regular and established place of business in Pittsburgh, PA, the License Agreement, and Defendants’ acts of infringing the Asserted Patents within this District and the State of Pennsylvania.

10. Venue is also proper in this District pursuant to 35 U.S.C. § 1400(b).

BACKGROUND OF THE COMMERCIAL DISPUTE

A. The Asserted Patents

11. The Asserted Patents were developed by Dr. Eric A. Nofzinger, a member of the University faculty for over 34 years. Dr. Nofzinger is an internationally recognized business-oriented Medical Research and Development Professional in the Neurosciences, Psychiatry, Neurology, and Sleep Medicine areas.

12. United States Patent No. 9,089,400 (the “’400 patent”) is titled “Methods, devices, and systems for treating insomnia by inducing frontal cerebral hypothermia” and was filed on April 22, 2013. The United States Patent and Trademark Office issued the ’400 patent on July 28, 2015. The ’400 patent is a continuation-in-part of application No. 12/288,417, filed on October 20, 2008. A true and correct copy of the ’400 patent is attached hereto as Exhibit B.

13. United States Patent No. 9,492,313 (the “’313 patent”) is titled “Methods and apparatus of noninvasive, regional brain thermal stimuli for the treatment of neurological disorders” and was filed on October 20, 2008. The United States Patent and Trademark Office issued the ’313 patent on November 15, 2015. The ’313 patent issued from application No. 12/288,417. A true and correct copy of the ’313 patent is attached hereto as Exhibit C.

14. United States Patent No. 9,669,185 (the “’185 patent”) is titled “Methods, devices, and systems for treating insomnia by inducing frontal cerebral hypothermia” and was filed on June 24, 2015. The United States Patent and Trademark Office issued the ’185 patent on June 6, 2017. The ’185 patent is a continuation the ’400 patent. A true and correct copy of the ’185 patent is attached hereto as Exhibit D.

15. The Asserted Patents claims patent-eligible subject matter and are valid and enforceable.

16. Dr. Nofzinger conveyed to the University all rights, title, and interest in and to the inventions of the Asserted Patents and their underlying patent applications by written assignments recorded in the United States Patent and Trademark Office.

17. The University is the exclusive owner by assignment of all rights, title, and interest in the Asserted Patents, including the rights to this suit for damages.

18. The Asserted Patents generally cover methods for treating insomnia by non-invasive hypothermic treatment that enable cooling of the forehead prior to and/or during sleep.

19. The cooling of the forehead reduces the metabolism, which is proven to improve sleep.

20. In general, the claimed methods include at least one thermal transfer region (*e.g.*, thermal transfer pad), which is configured to cool the skin above the forehead.

B. The License Agreement

21. The University is the Licensor of the License Agreement. *See* Exhibit A at 1.

22. Ebb Therapeutics, Inc. f/k/a Cerêve Inc. is the Licensee of the License Agreement. *See id.*

23. “[T]o induce University to enter to this [License] Agreement,” the Licensee “represented to University . . . that Licensee is experienced in the development, production, manufacture, marketing and sale of products and/or the use of similar products to the Licensed Products and Know-how that Licensee shall commit itself to a thorough, vigorous and diligent program of exploiting the Patent Rights so that public utilization results therefrom.” *Id.*

24. The Asserted Patents are continuations and/or continuations-in-part of United States patent applications listed in Exhibit A of the License Agreement and, therefore, are included in the “Patent Rights” of the License Agreement.

25. Under the terms of the License Agreement, the University granted to the Licensee:

(a) the exclusive right and license (subject to the University’s reservation of rights below) in the Territory to practice under the Patent Rights in the Field to the end of the term for which the Patent Rights are granted, unless this Agreement is terminated sooner as provided herein; and

(b) the non-exclusive right and license in the Territory to use Know-how in the Field, to practice under the Patent rights in the Field to the end of the term for which the Patent Rights are granted, unless this Agreement is terminated sooner as provided herein.

Exhibit A at Article 2.1.

26. “Know-how” is defined in the License Agreement as “the research data, whether or not patented, existing as of the Effective Date of this Agreement, and which was developed through research in the laboratory of Dr. Eric A. Nofzinger at or on behalf of the University of Pittsburgh that solely relate to and are required for the use or practice of the Patent Rights”

Exhibit A at Article 1.4.

27. “In consideration of the rights, privileges and license granted by the University hereunder,” Licensee agreed to “pay royalties and other monetary consideration” per the terms of Article 4 of the License Agreement.

28. Licensee also agreed to pay the University, *inter alia*, an initial license fee, annual maintenance fees, and royalties in an amount equal to Two and a Half Percent (2.5%) of Net Sales on any Licensed Product covered by a Valid Patent Claim and One Percent (1%) of Net Sales on any other Licensed Product. Exhibit A at Article 4.1(a)-(c).

29. Licensee also agreed to pay to the University a “milestone payment” “within thirty (30) business days of the sale of all, or substantially all, of the assets of” Licensee to be “calculated as One Percent (1%) of the Net Proceeds resulting from said transaction, provided that such payment shall not exceed Four Million Dollars (\$4,000,000).” Exhibit A at Article 4.1(g).

30. The purpose of Article 4.1(g) is for the University, in partial consideration for the license rights granted to the Licensee under the License Agreement, to benefit from the potential upside of Licensee by receiving a milestone payment in the event that Licensee experiences an exit transaction.

31. Article 6.1 grants the Licensee the “right to control the filing, prosecution, and maintenance of the Patent Rights in the United States”

32. Pursuant to Article 6.1, the Licensee controlled the prosecution of the patent applications for the Asserted Patents and received notices of issuance of the Asserted Patents. The Licensee was therefore on notice of the Asserted Patents by at least the time of issuance.

33. Article 9 of the License Agreement states (with emphasis added):

This Agreement is not assignable without the prior written consent of University, which shall not be unreasonably withheld or delayed, and any attempt to do so shall be null and void.

Notwithstanding the foregoing, Licensee may assign this Agreement and the license granted hereby without such prior consent to the purchaser of Licensee's **entire business**, whether by a merger, sale of assets, or otherwise; **provided however**, that such purchaser agrees in writing to be bound by the terms of this Agreement within thirty (30) days of such sale or transfer and a copy of such assumption agreement is provided to the University immediately thereafter.

C. The Acquisition

34. On December 9, 2020, Licensee was involved in an Acquisition which involved (1) its merger with Ebb Merger Sub, Inc., while retaining the name of Ebb Therapeutics, Inc.; (2) the merger of Ebb Therapeutics, Inc. with Second Ebb Merger Sub, LLC, while changing its name to Ebb Therapeutics, LLC, which is a wholly owned subsidiary of Kryo, Inc., such that Licensee did not survive these mergers, (3) the resignation of all of Licensees officers and directors and the termination of substantially all of Licensee's personnel, and (4) the receipt by Licensee (including its stockholders) of at least \$30,000,000 (as Licensee has represented to the University) in Net Proceeds in consideration for this Acquisition. True and correct copies of the merger documents on file with the Delaware Secretary of State are attached hereto as Exhibits E-F.

35. The Licensee did not seek the University's written consent prior to the Acquisition.

36. The Acquisition represents an exit transaction that triggers a milestone payment to the University per Article 4.1(g) within thirty (30) business days of the Acquisition.

37. Pursuant to Article 4.1(g), the University was due and owed at least \$300,000 as of January 8, 2021.

38. No milestone payment of at least \$300,000 to the University pursuant to Article 4.1(g) of the License Agreement has been made.

D. The License Agreement Termination

39. On January 22, 2021, the University wrote to Defendants to congratulate them on the Acquisition and to request information, documentation, and assurances demonstrating that Defendants have complied and will continue to comply with their obligations under the License Agreement. A true and correct copy of the January 22, 2021 correspondence is attached hereto as Exhibit G.

40. On February 5, 2021, Defendants wrote back to the University and confirmed Defendant Ebb Therapeutics, LLC—the surviving entity from the Acquisition—is now a wholly owned subsidiary of Defendant Kryo, Inc. Defendants declined to disclose further details related to the Agreement and Plan of Merger but denied that the Acquisition triggered the milestone payment under Article 4.1(g) of the License Agreement. Defendants only provided copies of the publicly available Certificates of Merger. A true and correct copy of the February 5, 2021 correspondence is attached hereto as Exhibit H.

41. On February 12, 2021, the University wrote to Defendants to provide written notice, pursuant to Article 10.1(a) of the License Agreement, that the Defendants were in breach, and the License Agreement would be terminated unless Defendants fully and properly cured the breach. A true and correct copy of the February 12, 2021 correspondence is attached hereto as Exhibit I.

42. On May 28, 2021, the University wrote to Defendants to confirm the License Agreement has been terminated, but the University explicitly stated the termination does not limit

or otherwise affect the Defendants' obligations under the License Agreement that accrued prior to termination. The University further demanded that Defendants pay the University at least \$300,00 pursuant to Article 4.1(g) no later than June 11, 2021. A true and correct copy of the May 28, 2021 correspondence is attached hereto as Exhibit J.

43. On June 10, 2021, Defendants wrote to the University "to advise the University of Pittsburgh that Kryo contends that no payments are due under the Exclusive License Agreement" Defendants further wrote "because it appears that both sides would like to terminate the Exclusive License Agreement immediately, Kryo and Ebb are willing to consider the Exclusive License Agreement to be terminated as of May 28, 2021." A true and correct copy of the June 10, 2021 correspondence is attached hereto as Exhibit K.

44. Throughout the term of the License Agreement the Licensee paid the University at least some if not all royalties due on products sold by the Licensee that practiced the defined Patent Rights, which covered the Asserted Patents, and/or incorporated the defined Know-how.

45. However, in its June 10, 2021 correspondence, Defendants had a change of heart and represented "[a]s Ebb continues to sell those products, Licensee does not intend to pay any further royalties to the University of Pittsburgh."

46. As of May 28, 2021, Defendants are not licensed under the Asserted Patents, either expressly or implicitly, nor do they enjoy or benefit from any rights in or to the Asserted Patents whatsoever.

47. As of May 28, 2021, Defendants are not licensed to use the Know-how, either expressly or implicitly, nor do they enjoy or benefit from any rights in or to the Know-how whatsoever.

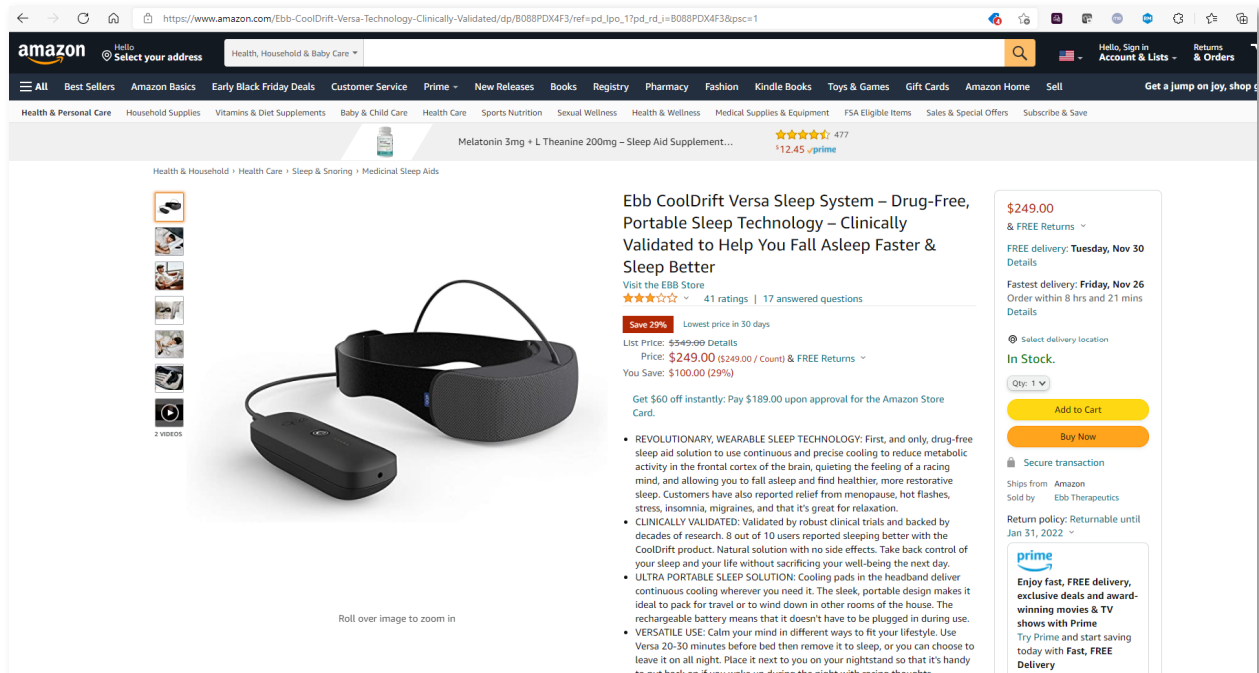
THE ACCUSED PRODUCTS

48. Defendants are in the business of designing, manufacturing, and selling devices that induce frontal cerebral hypothermia.

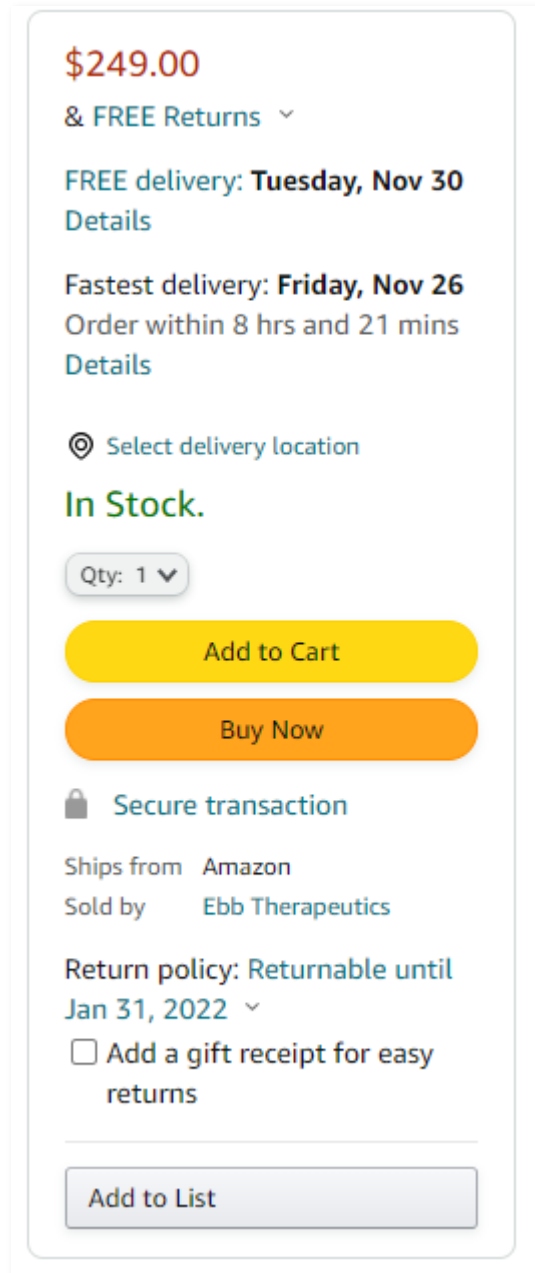
49. Defendants manufacture, use, and sell infringing Ebb-branded devices and products, including the Ebb CoolDrift Versa and the Ebb CoolDrift Luxe, which practice the Asserted Patents, including but not limited to: claim 1 of the '400 patent, claim 1 of the '313 patent, and claim 1 of the '185 patent.

50. The Ebb CoolDrift Versa and the Ebb CoolDrift Luxe also incorporate, were developed using, rely upon, and are marketed as being developed using the Know-how.

51. The Ebb CoolDrift Versa is available for purchase on Amazon.com. See https://www.amazon.com/Ebb-CoolDrift-Versa-Technology-Clinically-Validated/dp/B088PDX4F3/ref=pd_lpo_1?pd_rd_i=B088PDX4F3&psc=1.

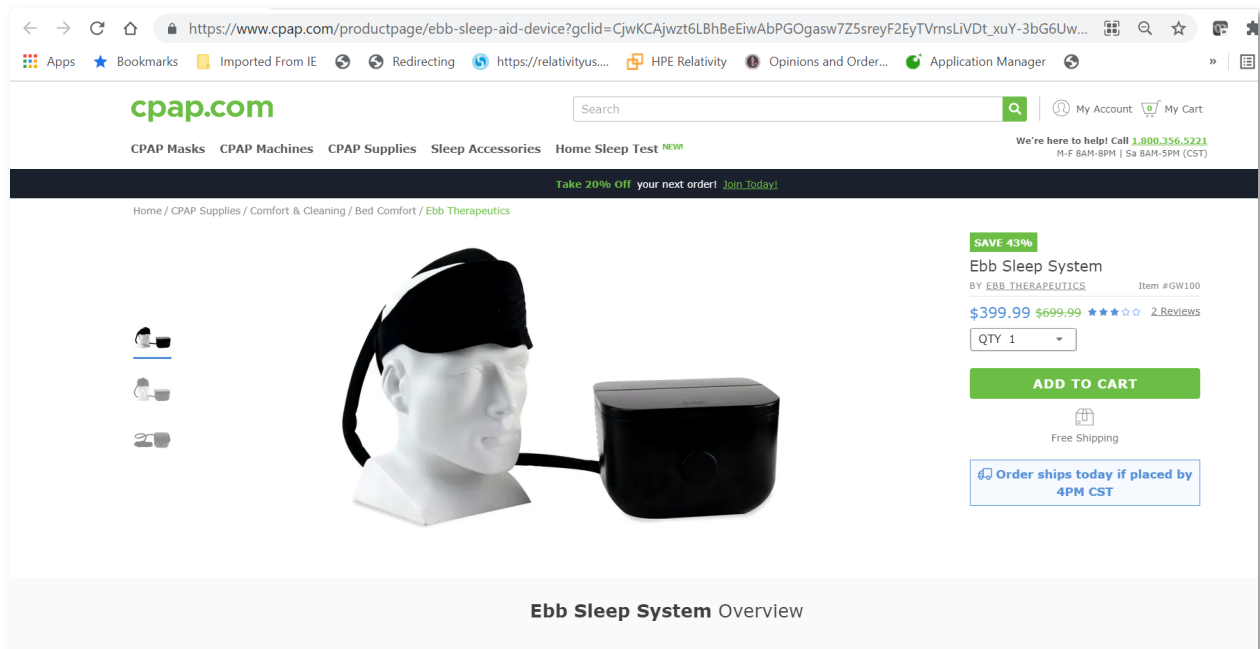


52. The Amazon.com listing page for the Ebb CoolDrift Versa states that the Ebb CoolDrift Versa is sold by Ebb Therapeutics. *See id.*

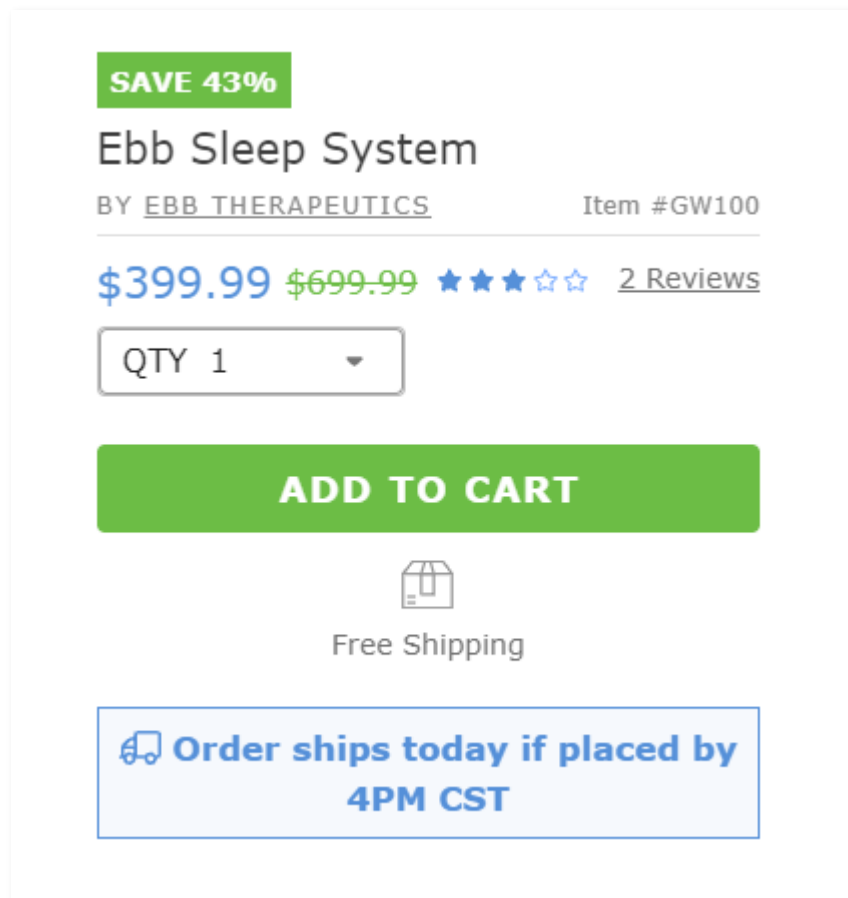


53. The Ebb CoolDrift Luxe is available for purchase on cpap.com. *See* <https://www.cpap.com/productpage/ebb-sleep-aid-device?gclid=CjwKCAjwzt6LBhBeEiwAb>

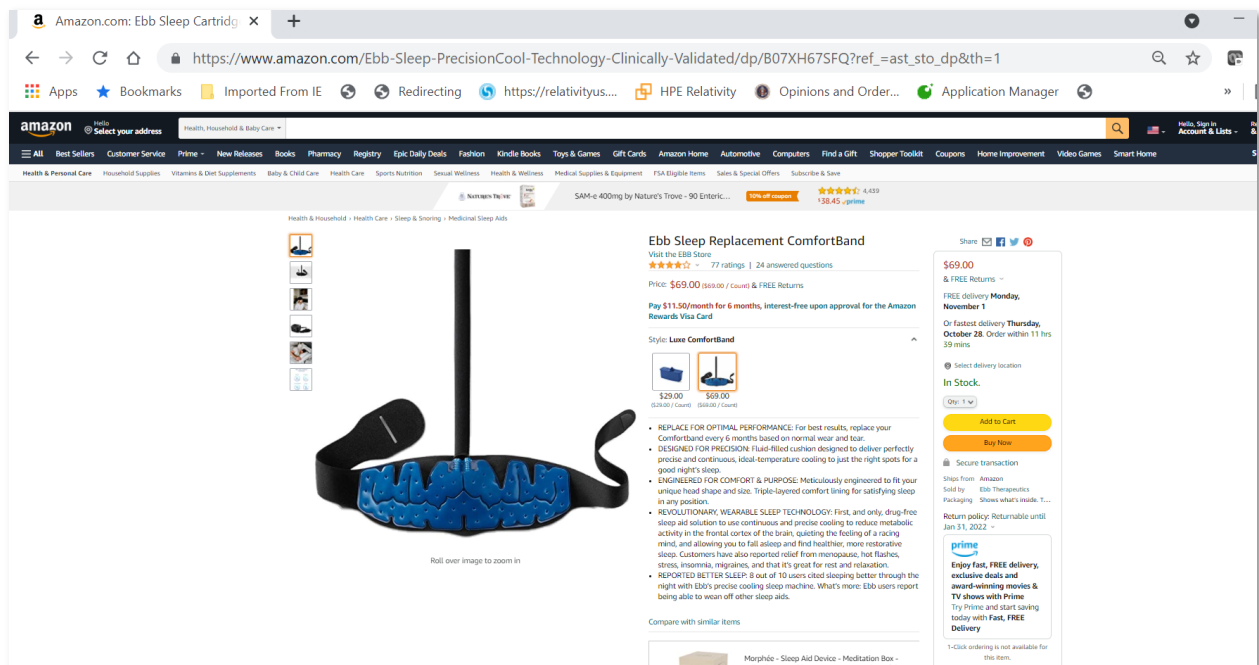
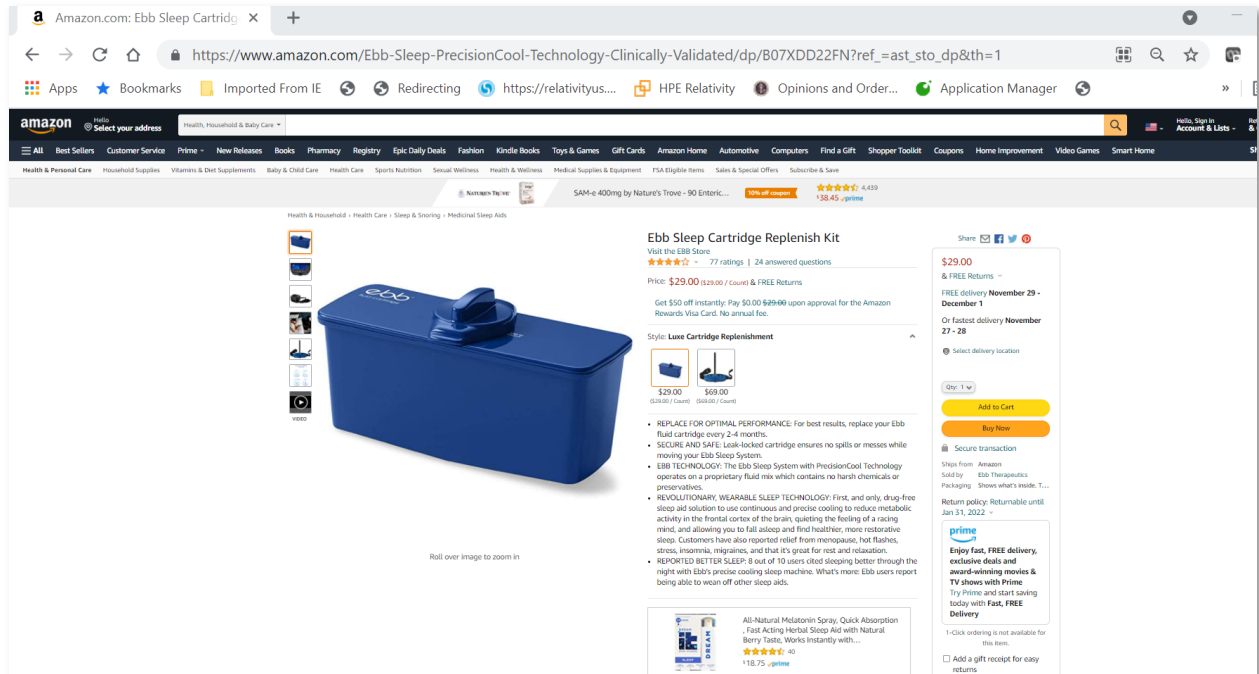
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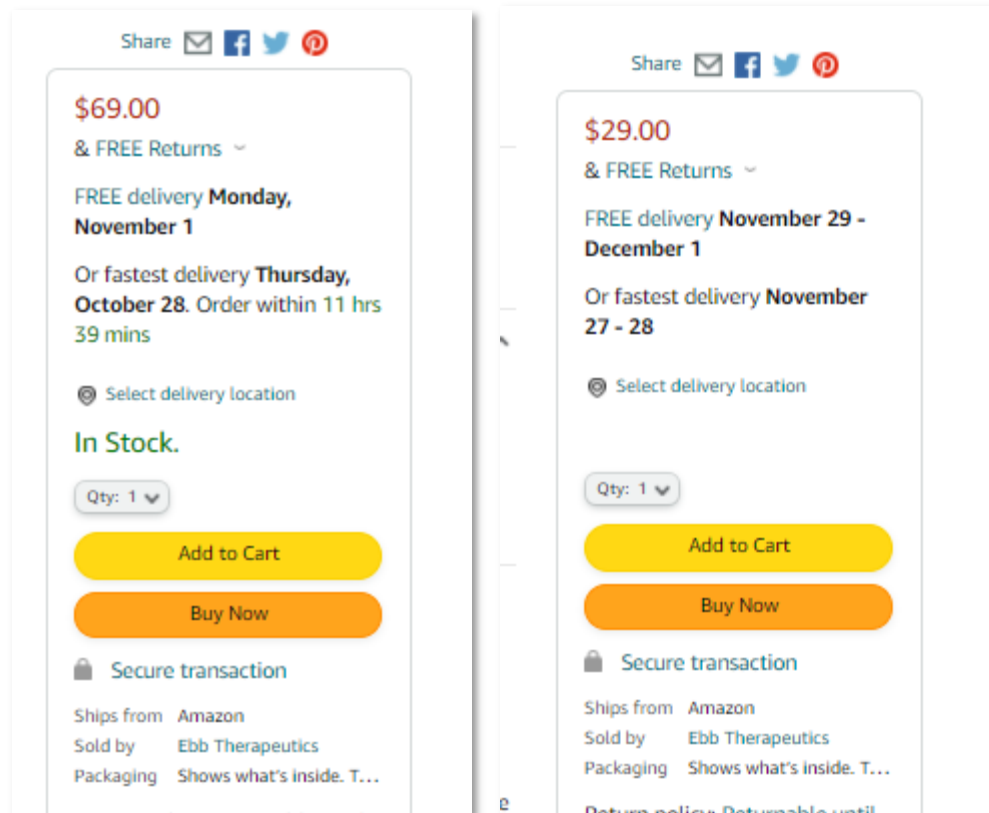
54. The cpap.com listing page for the Ebb CoolDrift Luxe states that the Ebb CoolDrift Luxe is sold by Ebb Therapeutics. *See id.*



55. Sleep Cartridge Replenish Kits and Comfort Bans for the Ebb CoolDrift Luxe are available for purchase on Amazon.com. See https://www.amazon.com/Ebb-Sleep-PrecisionCool-Technology-Clinically-Validated/dp/B07XDD22FN?ref_=ast_sto_dp&th=1.



56. The Amazon.com listing page for the Ebb CoolDrift Luxe Sleep Cartridge Replenish Kits and Comfort Bands states that they are sold by Ebb Therapeutics.



COUNT I: BREACH OF CONTRACT

57. All previous paragraphs are incorporated herein as if fully set forth.
58. The University is a signatory and the Licensor to the License Agreement.
59. The Defendants, as the successors-in-interest to the Licensee, have assumed all rights and responsibilities of the Licensee under the License Agreement.
60. Therefore, the University and the Defendants have a contractual relationship.
61. By failing to pay the University a milestone payment of one percent of the net proceeds resulting from the Acquisition, the Defendants have materially breached the License Agreement.
62. As a direct and proximate result of such actions, the University has suffered, and continues to suffer, injury in fact and has lost money in an amount believed to be at least \$300,000 plus interest, which will be proven at trial.

COUNT II: UNJUST ENRICHMENT

63. All previous paragraphs are incorporated herein as if fully set forth.

64. Pursuant to the License Agreement, the University shared Know-how with Defendants.

65. The Ebb CoolDrift Versa and the Ebb CoolDrift Luxe incorporate, were developed using, rely upon, and are marketed as being developed using the Know-how.

66. For example, Defendants rely on the results of a “pivotal study” performed by the University and published in the SLEEP Journal in May 2018 in advertising the effectiveness of Defendants’ products. See <https://www.ebbsleep.com/>.



67. By sharing with Defendants the University’s Know-how pursuant to the License Agreement, the University conferred a benefit on Defendants.

68. Defendants had knowledge of and appreciated that benefit.

69. Defendants accepted and retained that benefit after the termination of the License Agreement by continuing to sell the Ebb CoolDrift Versa and the Ebb CoolDrift Luxe products and accessories that incorporate the Know-how.

70. Allowing Defendants to fully retain the profits from unlicensed products and accessories that incorporate the Know-how without payment of value would be inequitable and unjust.

COUNT III: INFRINGEMENT OF THE '400 PATENT

71. All previous paragraphs are incorporated herein as if fully set forth.

72. Defendants have directly infringed and continue to directly infringe at least claim 1 of the '400 patent (either literally or under the doctrine of equivalents) without authority and in violation of 35 U.S.C. § 271(a) by making, using, selling, offering to sell, and/or importing into the United States the Accused Products that satisfy each and every limitation of at least claim 1 of the '400 patent.

73. The Accused Products reduce sleep onset by non-invasively applying hypothermal therapy to a subject's frontal cortex by positioning an applicator comprising a thermal transfer region in communication with the subject's skin over the subject's prefrontal cortex. Indeed, the Ebb Product Manual states: "Ebb . . . uses a **proprietary cooling headband** to naturally trigger a reduction in brain activity, which quiets the racing mind to help people with sleeplessness to fall asleep faster and get in to deeper stages of more restorative sleep faster."

Ebb

Device Description

Ebb is the first smart-technology and drug-free wearable device that uses a proprietary cooling headband to naturally trigger a reduction in brain activity, which quiets the racing mind to help people with sleeplessness to fall asleep faster and get in to deeper stages of more restorative sleep faster.

Ebb includes a bedside controller, headband, fluid cartridge, and power supply.

The intelligent bedside controller precisely regulates within the validated therapeutic temperature range (59-64°F).

The comfortable one-size-fits-all headband delivers consistent temperature and even cooling therapy across the forehead throughout the night.

Ebb Product Manual at 8 (emphasis added). A true and correct copy of the Ebb Product Manual is attached hereto as Exhibit L.

74. The Accused Products pass cooled fluid through the applicator so that the thermal transfer region is cooled to a first temperature between about 10° C. and about 25° C. *See id.* (“Ebb includes a bedside controller, **headband, fluid cartridge**, and power supply. The intelligent bedside controller regulates **within the validated therapeutic temperature range (59-64°F.)**” [*i.e.*, 15 to 17.778 °C.]) (emphasis added).

75. The Accused Products maintain the first temperature for a first time period extending at least 15 minutes. *See id.* (“Ebb includes a bedside controller, headband, fluid cartridge, and power supply. The intelligent bedside controller **regulates** within the validated therapeutic temperature range (59-64°F). The comfortable on-size-fits-all headband delivers **consistent** temperature and **even cooling therapy across the forehead throughout the night.**”) (emphasis added).

76. Defendants have indirectly infringed and continue to indirectly infringe at least claim 1 of the ’400 patent without authority and in violation of 35 U.S.C. § 271(b) by knowingly and intentionally inducing others, including end users of the Accused Products, to directly infringe (either literally or under the doctrine of equivalents), by making, using, offering to sell, selling, and/or importing into the United States the Accused Products that practice at least the method covered by claim 1 of the ’400 patent.

77. Defendants, with knowledge that the Accused Products, or the use thereof, infringe at least claim 1 of the ’400 patent by knowingly and intentionally inducing, and continuing to knowingly and intentionally induce, direct infringement of at least claim 1 of the ’400 patent by providing these Accused Products to end users for use in an infringing manner.

78. Defendants induced infringement by others, including end users, with the intent to cause infringing acts by others or, in the alternative, with the belief that there was a high probability that others, including end users, infringe at least claim 1 of the '400 patent.

79. Defendants have indirectly infringed and continue to indirectly infringe at least claim 1 of the '400 patent without authority and in violation of 35 U.S.C. § 271(c) by knowingly and intentionally contributing to the direct infringement (either literally or under the doctrine of equivalents) by end users of the Accused Products by making, using, offering to sell, selling, and/or importing into the United States the Accused Products that practice the methods covered by the '400 patent, knowing the Accused Products are especially made and/or adapted for use in direct infringement of the '400 patent. The Accused Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

80. The University has suffered damages as a result of Defendants' direct and indirect infringement of the '400 patent in an amount to be proven at trial.

81. The University has suffered, and will continue to suffer, irreparable harm as a result of Defendants' infringement of the '400 patent for which there is no adequate remedy at law, unless Defendants' infringement is enjoined by this Court.

COUNT IV: INFRINGEMENT OF THE '313 PATENT

82. All previous paragraphs are incorporated herein as if fully set forth.

83. Defendants have directly infringed and continue to directly infringe at least claim 1 of the '313 patent (either literally or under the doctrine of equivalents) without authority and in violation of 35 U.S.C. § 271(a) by making, using, selling, offering to sell, and/or importing into the United States the Accused Products that satisfy each and every limitation of at least claim 1 of the '313 patent.

84. The Accused Products treat insomnia in a patient in need of such treatment by applying noninvasive, regional brain cooling to a region of a patient's head over a forehead and a temporal region of the patient's skull to locally cool the patient's forehead and the patient's temporal region by applying a temperature of between 10° C. and 28° C. prior to sleep, wherein the patient has insomnia and wherein applying comprises circulating a temperature-controlled fluid through an applicator on the patient's head. Indeed, the Ebb Product Manual states: "Ebb . . . uses **a proprietary cooling headband** to naturally trigger a reduction in brain activity, which quiets the racing mind **to help people with sleeplessness** to fall asleep faster and get in to deeper stages of more restorative sleep faster." *See* Exhibit L at 8. The Ebb Product Manual further states: "Ebb includes a bedside controller, headband, **fluid cartridge**, and power supply. **The intelligent bedside controller regulates** within the validated therapeutic temperature range **(59-64°F.)**" [*i.e.*, 15 to 17.778 °C.]) *Id.* (emphasis added).

85. The Accused Products maintain the temperature between 10° C. and 28° C. to reduce brain metabolism in one or more of the patient's frontal cortex, prefrontal cortex and temporal cortex. *See id.* at 8 ("The intelligent bedside controller **regulates** within the validated therapeutic temperature range (59-64°F.)" [*i.e.*, 15 to 17.778 °C.]) (emphasis added).

86. The Accused Products allow the patient to fall asleep. *See id.* at 3 ("Ebb is the first, smart-technology and drug-free device that uses a proprietary cooling headband to precisely maintain the forehead at a cool temperature ideal for a **good night's sleep.**") (emphasis added).

87. Defendants have indirectly infringed and continue to indirectly infringe at least claim 1 of the '313 patent without authority and in violation of 35 U.S.C. § 271(b) by knowingly and intentionally inducing others, including end users of the Accused Products, to directly infringe (either literally or under the doctrine of equivalents) by making, using, offering to sell, selling,

and/or importing into the United States the Accused Products that practice at least the method covered by claim 1 of the '313 patent.

88. Defendants, with knowledge that the Accused Products, or the use thereof, infringe at least claim 1 of the '313 patent by knowingly and intentionally inducing, and continuing to knowingly and intentionally induce, direct infringement of at least claim 1 of the '313 patent by providing these Accused Products to end users for use in an infringing manner.

89. Defendants induced infringement by others, including end users, with the intent to cause infringing acts by others or, in the alternative, with the belief that there was a high probability that others, including end users, infringe at least claim 1 of the '313 patent.

90. Defendants have indirectly infringed and continue to indirectly infringe at least claim 1 of the '313 patent without authority and in violation of 35 U.S.C. § 271(c) by knowingly and intentionally contributing to the direct infringement (either literally or under the doctrine of equivalents) by end users of the Accused Products by making, using, offering to sell, selling, and/or importing into the United States the Accused Products that practice the methods covered by the '313 patent, knowing the Accused Products are especially made and/or adapted for use in direct infringement of the '313 patent. The Accused Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

91. The University has suffered damages as a result of Defendants' direct and indirect infringement of the '313 patent in an amount to be proven at trial.

92. The University has suffered, and will continue to suffer, irreparable harm as a result of Defendants' infringement of the '313 patent for which there is no adequate remedy at law, unless Defendants' infringement is enjoined by this Court.

COUNT V: INFRINGEMENT OF THE '185 PATENT

93. All previous paragraphs are incorporated herein as if fully set forth.

94. Defendants have directly infringed and continue to directly infringe at least claim 1 of the '185 patent (either literally or under the doctrine of equivalents) without authority and in violation of 35 U.S.C. § 271(a) by making, using, selling, offering to sell, and/or importing into the United States the Accused Products that satisfy each and every limitation of at least claim 1 of the '185 patent.

95. The Accused Products enhance sleep by non-invasively applying hypothermal therapy to at least a portion of a subject's frontal cortex, prefrontal cortex, or frontal and prefrontal cortex by positioning an applicator comprising a thermal transfer region in communication with the subject's skin over at least a portion of the subject's frontal cortex, prefrontal cortex, or frontal and prefrontal cortex." Indeed, the Ebb Product Manual states: "Ebb . . . uses a **proprietary cooling headband** to naturally trigger a reduction in brain activity, which quiets the racing mind to help people with sleeplessness to fall asleep faster and get in to deeper stages of more restorative sleep faster." Exhibit L at 8 (emphasis added).

96. The Accused Products maintain the applicator temperature so that the thermal transfer region is cooled to between about 10° C. and about 25° C. *See id.* at 8 ("The intelligent bedside controller **regulates within the validated therapeutic temperature range (59-64°F.)**" [*i.e.*, 15 to 17.778 °C.]

97. The Accused Products maintain the temperature for a time period extending at least 15 minutes. *See id.* ("Ebb includes a bedside controller, headband, fluid cartridge, and power supply. The intelligent bedside controller **regulates** within the validated therapeutic temperature

range (59-64°F). The comfortable on-size-fits-all headband delivers **consistent** temperature and **even cooling therapy across the forehead throughout the night.**") (emphasis added).

98. Defendants have indirectly infringed and continue to indirectly infringe at least claim 1 of the '185 patent without authority and in violation of 35 U.S.C. § 271(b) by knowingly and intentionally inducing others, including end users of the Accused Products, to directly infringe (either literally or under the doctrine of equivalents) by making, using, offering to sell, selling, and/or importing into the United States the Accused Products that at least the method covered by claim 1 of the '185 patent.

99. Defendants, with knowledge that the Accused Products, or the use thereof, infringe at least claim 1 of the '185 patent by knowingly and intentionally inducing, and continuing to knowingly and intentionally induce, direct infringement of at least claim 1 of the '185 patent by providing these Accused Products to end users for use in an infringing manner.

100. Defendants induced infringement by others, including end users, with the intent to cause infringing acts by others or, in the alternative, with the belief that there was a high probability that others, including end users, infringe at least claim 1 of the '185 patent.

101. Defendants have indirectly infringed and continue to indirectly infringe at least claim 1 of the '185 patent without authority and in violation of 35 U.S.C. § 271(c) by knowingly and intentionally contributing to the direct infringement (either literally or under the doctrine of equivalents) by end users of the Accused Products by making, using, offering to sell, selling, and/or importing into the United States the Accused Products that practice the methods covered by the '185 patent, knowing the Accused Products are especially made and/or adapted for use in direct infringement of the '185 patent. The Accused Products are not a staple article or commodity of commerce suitable for substantial non-infringing use.

102. The University has suffered damages as a result of Defendants' direct and indirect infringement of the '185 patent in an amount to be proven at trial.

103. The University has suffered, and will continue to suffer, irreparable harm as a result of Defendants' infringement of the '185 patent for which there is no adequate remedy at law, unless Defendants' infringement is enjoined by this Court.

JURY DEMAND

104. The University hereby demands a trial by jury for all causes of action.

PRAYER FOR RELIEF

105. The University requests the following relief:

- A. Entry of Judgment declaring that Defendants have breached the License Agreement;
- B. Entry of Judgment declaring that Defendants have been unjustly enriched;
- C. Entry of Judgment declaring that Defendants have directly and/or indirectly infringed one or more claims of each Asserted Patent;
- D. Entry of Judgment declaring that Defendants' infringement of the Asserted Patents is willful;
- E. An order awarding damages sufficient to compensate the University for Defendants' breach of contract, unjust enrichment, and infringement of the Asserted Patents, but in no event less than the milestone payment that is owned under Article 4.1(g), outstanding royalty payments, a reasonable ongoing royalty, supplemental damages post-verdict, together with pre-judgment and post-judgment interest and costs;
- F. Enhanced damages pursuant to 35 U.S.C. § 284;
- G. Entry of Judgment declaring that this case is exceptional and awarding the University its costs and reasonable attorney fees under, *inter alia*, 35 U.S.C. § 285;
- H. An accounting for acts of infringement;
- I. Such other equitable relief which may be requested and to which the University is entitled; and
- J. Such other equitable relief as the Court deems just and proper.

Dated: November 24, 2021

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

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